

Understanding Aducanumab

An Information Guide for Patients

Currently, an estimated 6 million Americans are living with Alzheimer's, the most common cause of dementia.

In June 2021, the Food and Drug Administration (FDA) granted accelerated approval to aducanumab (Aduhelm™), the first treatment approved for Alzheimer's disease since 2003 and the first to address its underlying biology.

While not a cure, this new treatment could mean more time for individuals to actively participate in daily life, have sustained independence and hold on to memories longer. This drug may work differently for everyone who takes it, and may not work for some individuals.

The Alzheimer's Association® has created this information guide to help you understand the new treatment. People who are interested in learning more should have a conversation with their health care provider.

HOW DOES ADUCANUMAB WORK?

Amyloid is a protein that clumps into sticky brain plaques, one of the hallmarks of Alzheimer's disease. Many researchers believe that these small clumps may contribute to the cell death and tissue loss observed in the brains of individuals with Alzheimer's disease.

Based on their review, the FDA determined that there is substantial evidence that aducanumab reduces amyloid plaques in the brain and that the reduction in these plaques is reasonably likely to

reduce cognitive and functional decline in people living with early Alzheimer's.

WHO IS A CANDIDATE FOR THE TREATMENT?

The FDA specified the treatment should be initiated in patients in the Alzheimer's disease stage studied in the clinical trials — people with mild cognitive impairment (MCI) or mild dementia stage of disease. The people studied in aducanumab trials also showed evidence of a buildup of amyloid plaques in the brain.

The FDA is not directly requiring any specific diagnostic test. However, the label says the treatment is indicated for the treatment of Alzheimer's disease, based on reduction in amyloid plaques, one of the hallmarks of Alzheimer's and required for the diagnosis of Alzheimer's disease. This means that a physician should confirm the presence of amyloid plaques in the brain before prescribing this anti-amyloid plaque treatment. Confirmatory tests like cerebrospinal fluid analysis or amyloid positron emission tomography (PET) imaging should be a part of the diagnostic process to determine eligibility for the treatment.



The therapy has not yet been tested on people with more advanced cases of dementia due to Alzheimer's disease or those without symptoms. Assessment of the treatment benefit over time will be done with the patient's health care provider, and treatment may need to stop at some point if the drug is no longer demonstrating benefit to the patient.

WHAT ARE THE SIDE EFFECTS?

All drugs have side effects. In the FDA label, most common side effects include amyloid-related imaging abnormalities (ARIA), headache and fall. Another potentially serious side effect is allergic reaction.

ARIA is a common side effect that usually does not cause any symptoms, but can be serious. It is typically a temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain with the swelling, although most people with swelling in areas of the brain do not have symptoms. Some may have symptoms of ARIA such as headache, dizziness, nausea, confusion and vision changes. As part of the treatment and monitoring for risk of ARIA in patients receiving this therapy, MRI scans are required by the FDA before and during the treatment.

Some factors, including genetics, certain medications and other health conditions, may increase risk for ARIA. As with any treatment, it is important to have a conversation with your health care provider to determine if you are a candidate, learn about side effects, and make an informed decision to determine if this treatment is an option for you or someone you know.

HOW IS THE TREATMENT ADMINISTERED?

The treatment is administered intravenously through an IV infusion every four weeks, and each treatment is expected to last 45 to 60 minutes.

While we do not yet have information on specific locations, in general, infusions can be done at

hospitals, infusion therapy centers and, in some cases, in a person's home by specialized nurses.

It is unclear how many doses any individual will need to take over the course of their treatment. The clinical trial tested this drug over the course of 18 months and many people have been treated for years.

HOW CAN I ACCESS THE TREATMENT?

Now that the treatment is approved, nationwide distribution and implementation will take some time.

If you have a diagnosis of MCI due to Alzheimer's or mild (early) Alzheimer's dementia, talk to your doctor to determine if you are a candidate for the treatment or to discuss all treatment options. Your primary care physician may not be able to prescribe the treatment. He or she can provide a preliminary assessment and may refer you to a specialist to determine if it is an appropriate treatment for you.



WHAT IF I DON'T HAVE A DIAGNOSIS?

With the accelerated approval of aducanumab, early detection and diagnosis is even more critical to ensure individuals with the disease can talk to their doctor about this new treatment and determine if they may be a candidate.

If you or someone you know is noticing changes to memory or thinking, it's important to share your concerns with your doctor. You may be referred to

a specialist for a definitive diagnosis and to determine appropriate treatment.

Early diagnosis can also allow the person living with the disease and their caregivers to better manage medications, build a care team, receive counseling and other support services, create advance directives, and address driving and safety concerns.



IS THE COST OF THE TREATMENT COVERED BY INSURANCE?

At this time, we do not know what insurance coverage will be for aducanumab or how Medicare will cover this treatment. The Centers for Medicare & Medicaid Services (CMS) recently announced a National Coverage Analysis, during which they will seek input from the public and make a coverage decision. That decision is expected in spring of 2022. The Alzheimer's Association is committed to working with CMS — as well as with the private payer community — to ensure coverage for the drug, any tests needed during the diagnostic or treatment process, and other associated costs for all who would benefit.

DID THE CLINICAL TRIALS FOR THIS DRUG INCLUDE DIFFERENT RACES AND ETHNICITIES?

Diverse populations have been historically underrepresented in clinical trials, and the same is true for this clinical trial data.

We do not know whether this drug will consistently reduce the level of amyloid plaques in the brains

of people from underrepresented populations. However, the inverse is also true: There is no evidence that anti-amyloid drugs will not work in people from underrepresented populations if they have evidence of amyloid buildup in their brains.

It is true that people from underrepresented populations are often diagnosed later in the course of the disease, and are misdiagnosed more often. This will likely have an impact on their ability to access the drug.

At the same time, it is a powerful motivation to encourage earlier detection and more accurate diagnosis in everyone.

WHAT IF MY DOCTOR RECOMMENDS THE TREATMENT BUT I DON'T WANT IT, OR WANT TO WAIT?

As with any treatment, it is important to discuss potential benefits, risks and concerns with your doctor. Ultimately, it is up to the patient to decide whether or not to pursue treatment. Alzheimer's is a progressive disease, where dementia symptoms gradually worsen over a number of years. The FDA has specified that the treatment should be initiated in patients in the Alzheimer's disease stage studied in the clinical trials — people with MCI or mild dementia stage of disease. Therefore, those who decide to wait to pursue treatment should have a conversation with their doctor when they are ready to determine if they are still eligible.

The Alzheimer's Association is here all day, every day for people facing Alzheimer's and other dementia through our free 24/7 Helpline at **800.272.3900** and website at **alz.org**.

We also provide care and support through online services and in-person programs in communities nationwide.